UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,557	07/16/2001	Takahiko Ishiguro	Q65441	6024

65565 7590 11/30/2007

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
11/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/904,557	ISHIGURO ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/11/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed September 11, 2007. This action is made non-final.

Claims 13-15 are currently pending. No claims have been amended. Claims 13-15 are addressed herein.

Withdrawn Objections

2. The objection made over Fig 6A in section 2 of the Office Action of June 11, 2007 is withdrawn in view of the submission of a replacement for Fig 6A.

The objection made over the specification in section 3 of the Office Action of June 11, 2007 is withdrawn in view of amendments made to the specification and in view of Applicants compliance to the sequence requirements.

Withdrawn Rejections

3. The rejection made under 35 USC 102 (b) in section 5 of the Office Action of June 11, 2007 is withdrawn in view of Applicants arguments. Specifically the Applicants argued that Lockhart does not teach that first strand cDNA synthesis is initiated using an oligonucleotide that contains a region that is complementary to at least 10 continuous nucleotides because Lockhart uses an oligo dT primer. This argument has been found persuasive, therefore this rejection is withdrawn. However a new art rejection is set forth below.

The rejection made under 35 USC 103 (a) in section 7 of the Office Action of June 11, 2007 is withdrawn in view of Applicants arguments. Specifically these rejections depend on the Lockhart reference which does not teach all of the claim limitations. Therefore this rejection is withdrawn. However a new art rejection is set forth below.

The double patenting rejection made over copending application 10939468 in section 8 of the Office Action of June 11, 2007 is withdrawn in view of the abandonment of application 10939468.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Hayes (Journal of Clinical Pathology 1999) as evidenced by Kondo (US Patent 5853981 Issued 12/1998).

Regarding Claim 13A Hayes teaches a method which comprises obtaining RNA transcripts from human individuals infected with EBV. In the instant case the selected DNA molecule is the EBV genomic sequence (page 99 col 1&2 and page 100 col 1).

Regarding Claim 13B Hayes teaches screening selected portions of the EBV genomic sequence. The selected portions are regions that encode homologues to important human proteins. Specifically the regions encode the vIL-10, BDLF2, and BARF1 proteins (table 3). The nucleotide sequence of each of these regions is known. The purpose of this study was to determine which regions were expressed in different types of EBV infections (page 98 col 1).

Regarding Claim 13i Hayes teaches that the RNA transcripts were amplified using first and second primers. To amplify vIL-10 the first primer was complementary to 19 continuous nucleotides located at or near the 3' end of the selected portion of the selected DNA molecule, and the second primer was complementary to 23 continuous nucleotides located at or near the 5'-end of said selected portion of said selected DNA molecule (table 3 oligo 1.1 and 2.1).

Regarding Claims 13a-d Hayes does not specifically recite each step of NASBA amplification, however as evidenced by Kondo NASBA comprises (a) forming a RNA-DNA duplex comprising one of the RNA transcripts and a complementary DNA molecule, by synthesizing a first DNA molecule complementary to the RNA transcript using a primer, an RNA-dependent DNA polymerase and one of the RNA transcripts (Column 4, lines 17-25); (b) preparing a single-stranded DNA molecule by hydrolyzing the RNA transcript of the RNA-DNA duplex using ribonuclease H (Column 4, lines 26-29); (c) forming a doubled-stranded DNA molecule comprising the single stranded DNA molecule of (b) and a complementary DNA molecule thereto, by synthesizing a second DNA molecule using a primer with a promoter sequence, a DNA-dependent DNA

polymerase, and the single-stranded DNA molecule of (b) as a template (column 4, lines 30-38); (d) forming an RNA transcription product using an RNA polymerase, wherein RNA transcription is primed from the RNA-transcriptable promoter sequence (column 4, lines 39-42); and (e) repeating steps (a) to (d) using the RNA transcription product of (d) as a template for the formation of the RNA-DNA duplex of (a) column 4, line 43-column 5, line 5). In the instant case the limitations recited in Claim 13 a-d are considered to be an inherent property of the NASBA method as demonstrated by Kondo.

Regarding Claim 13(ii) Hayes teaches that the amplification products were detected to thereby screen for a RNA transcript that is enocded by the selected portionof the selected DNA molecule (page 100 col 1).

Regarding Claim 13C, Hayes teaches a method of screening at least 3 selected portions of the EBV DNA molecule. Each portion (i.e. vIL-10, BDLF2, and BARF1) is different from and non overlapping with the other portions (table 3). Thus Hayes teaches repeating B on at least one other selected portion that is different from and non overlapping with the first selected portion.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes (Journal of Clinical Pathology 1999), as evidenced by Kondo (US Patent 5853981 Issued 12/1998) as applied to claim 13 above, and further in view of Ishiguro (Nucleic Acids Research 1996).

The teachings of Hayes are presented above.

Regarding Claims 14 and 15 Hayes teaches a method wherein the amplification product is detected using a probe which consists of a sequence that is not complementary to either the first or second oligonucleotide primer (table 3), however Hayes does not teach that the probe is labeled with an intercalating fluorescent dye. Further Hayes does not disclose an intercalating fluorescent dye that has a differential

fluorescence characteristic depending on whether said probe exists in an unbound single-stranded state or in a bound duplex with said amplification product.

However Ishiguro teaches a fluorescent intercalative dye-labeled probe which can recognize a specific nucleic acid sequence by linking a fluorescent intercalative dye as a label to a single-stranded oligonucleotide complementary in nucleic acid sequence to a specific nucleic acid sequence of the specific nucleic acid, so that when the single-stranded oligonucleotide hybridizes with the specific nucleic acid, the intercalative dye intercalates into the resulting double-stranded oligonucleotide to alter the florescent property (Abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hayes by using probes linked to fluorescent intercalative dyes as suggested by Ishiguro. One would have been motivated to use the probes described by Ishiguro since they enable detection and quantification of nucleotide specific hybrids, not just any double stranded hybrid (page 4994, col 2 to page 4995 col 1). Further all of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Additionally these claims would have been obvious because substitution of the probe taught by Hayes for the probe taught by Ishiguro would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

6. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER